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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,336

10/08/2004

Toshio Matsuda

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09/05/2006

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EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,336	Applicant(s) MATSUDA ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7-17 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-4,7-13 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 6/13/2006. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that there is no search burden. This is not found persuasive because a search for one group will not lead to information regarding another in the non-patent literature. The requirement is still deemed proper and is therefore made FINAL. Claim(s) 1-4, 7-17, 22-26 are pending. Claim(s) 12, 16, 24, 26 have been amended. Claim(s) 1-4, 7-13, 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim(s) 14-17 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the method of treating a motor nervous system or peripheral nervous system disease, does not reasonably provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of treating and preventing a motor nervous system or peripheral nervous system disease.

(2) State of the Prior Art: The state of the art regarding treating a motor nervous system or peripheral nervous system disease is relatively high, however the state of the art for the prevention of a motor nervous system or peripheral nervous system disease is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of a motor nervous system or peripheral nervous system disease.

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(4) Guidance of the Specification: The guidance of the specification as to the prevention of a motor nervous system or peripheral nervous system disease is completely lacking. The specification discloses preventing the onset of a motor nervous system or peripheral nervous system disease. However, the specification fails to mention how one is able to determine whether the onset of a motor nervous system or peripheral nervous system disease in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the specification fails to mention the complete prevention or cessation of a motor nervous system or peripheral nervous system disease once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing a motor nervous system or peripheral nervous system disease. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent a motor nervous system or peripheral nervous system disease, nor does the prior art reveal any type of prevention associated with a motor nervous system or peripheral nervous system disease.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent a motor nervous system or peripheral nervous system disease. Moreover, one is unable to determine whether a subject will ever develop a motor nervous system or peripheral nervous system disease should this subject be administered a compound of formula I.

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(7) Working Examples: The specification does not give any data for the prevention of a motor nervous system or peripheral nervous system disease.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of a motor nervous system or peripheral nervous system disease. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The structure is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The elected compounds in the instant invention are defined only by their function and not structure. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. It is not clear whether "(neuropathy, diabetic nervous disease)" as defined in parentheses is part of the limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Marston et al. (WO 98/27930).

Marston et al. teach the use of aminopiperazine derivatives of formula I (abstract) for the prevention and treatment of spinal cord injury and Parkinson's disease in mammals (pg. 1, lines 6-13). A preferred compound is N-(4-acetyl-1-piperazinyl)-4-fluorobenzamide (pg. 5, lines 28-29) and its hydrate form (pg. 6, lines 8-10).

Examiner respectfully notes that spinal cord injury as disclosed by Marston et al. reads on myelopathy, since it is defined as a disorder of the spinal cord.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER